Reference Number	SOP005 v1	Date October 2024
Title	Quality Assurance and Clinical Audit	
Purpose	The purpose of this SOP is to describe the process for reviewing quality assurance and clinical audits at Eastern Health.	

1. Scope

This SOP applies to all proposed quality assurance and/or clinical audit activity.

2. Target Audience

The target audiences are Eastern Health researchers (including delegates and collaborators), sponsors and contract research organisations.

3. Related Policies

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
3476	Clinical Quality Registries Guideline
SOP001	Research at Eastern Health
SOP002	Ethical Review
SOP003	Human Research Ethics Committee (HREC) Review
SOP004	Lower Risk

4. Definitions

Quality Assurance	An activity where the primary purpose is to monitor or improve the quality of service delivered by an individual or an organisation.
Clinical Audit	A systematic collection and review of clinical data. This does not include any collection of new raw data.
Research	An intellectual investigation aimed at discovering, interpreting and revising human knowledge.

Research Governance	A system for overseeing and ensuring that research is conducted legally, efficiently and ethically in compliance with the parameters set by the local and, if appropriate, the central approving ethics committee, community standards and the law.

5. Responsibilities

It is the responsibility of all Eastern Health investigators, collaborators, Institutes and their delegates, Sponsors and Contract Research Organisations, conducting research at Eastern Health, to follow and adhere to procedures set out in this SOP.

6. Procedure

It is recognised that the Human Research Ethics Committee (HREC) review process is not the optimal pathway to review, or it required to review, Quality Assurance (QA) and clinical audit activities. Instead, all QAs and clinical audits require registration with the Eastern Health Office of Research and Ethics (ORE), rather than a formal ethics review.

Even though QA and clinical audits do not require formal ethics review, the activity must be conducted in a way that is ethical. This should include consideration of whether the people involved will be exposed to any harm as a result of the activity. The Office of Research and Ethics take into consideration the following points when reviewing a QA/clinical audit submission –

- Does the project benefit Eastern Health or lead to improvement of services within Eastern Health?
- Are participants afforded appropriate protections and respect?
- Is there adherence to relevant ethical principles and state legislation?
- Are all relevant Eastern Health governance requirements satisfied? Eg. Privacy and data security, professional standards

QA and clinical audit activities are approved for 1 year from registration unless otherwise stated.

Upon completion, submission of formal final reports to the Office of Research and Ethics are not required. All aspects of the QA/audit activity should be maintained by the Principal Investigator.

7. Related Material

Consult the Eastern Health Office of Research and Ethics (ORE) website for advice and any forms required for submissions. Eastern Health Institute | Eastern Health

8. References

Internal References

2959	Ethical and Responsible Conduct of Research Standard
2961	Ethical and Governance Review of Research
2321	Research at Eastern Health Policy
3476	Clinical Quality Registries Guideline
SOP001	Research at Eastern Health
SOP002	Ethical Review
SOP003	Human Research Ethics Committee (HREC) Review
SOP004	Lower Risk

External References

NHMRC National Statement of Ethical Conduct in Human Research (2023)
NHMRC Australian Code for Responsible Conduct of Research (2018)
ETHICAL CONSIDERATIONS IN QUALITY ASSURANCE AND EVALUATION ACTIVITIES National Health and Medical Research Council - Published: March 2014

9. Further Information

For enquiries related to this Standard Operating Procedure please email ethics@easternhealth.org.au

10. Version History

Date	Version	Author	Authoriser	Summary of Changes	Next Revision Due
October 2024	1	Ms Sharon Reid – Research Governance Manager	Prof David Taylor – Director of Research	Not applicable – first version	October 2025